

REMARKS

The claims have been amended in response to the rejection under 35 U.S.C. § 112, paragraph 2. In claim 1, “an” is added before analyte. Although “concentration” has not been referred to previously to “the concentration,” applicants believe the definite article is proper because this is specifically what is being measured.

Claim 1 has also been amended to include the possibility that, in addition to a “light absorbing moiety” the decrease in detected light that is proportional to the analyte concentration may also be effected by a moiety that physically interacts with the light emitting moiety to inhibit emission. This possibility is supported in paragraph 10 on page 3. Claims 2-4 have been amended accordingly and new claims 10 and 11 separately claim the alternatives of a “light absorbing moiety” or a “moiety that physically interacts with the light emitting moiety to inhibit light emission.”

Claim 4 has been amended to delete “the” in three places. “The reagents” in claim 6 refers to the reagents in line 4 of claim 1. Applicant has also amended claim 7 for clarification. Claims 8 and 9 are added to specify that the light-emitting moiety is a fluorescent compound. No new matter is added and entry of the amendment is respectfully requested.

In response to the request made by the Examiner to explain how the present continuation-in-part differs from the parent application 08/469,806, applicant notes simply that the substance of the earlier application has been incorporated by reference and the description has been rewritten to focus on what is intended to be claimed. Unnecessary drawings have been deleted. The experimental results presented in the present application are also present in the parent.

The Rejection Under 35 U.S.C. § 102(b)

All claims were rejected as assertedly anticipated by Morris, U.S. 5,173,434. While Morris discloses a modification to colorimetric or turbidimetric assays based on quenching of fluorescence, the method of the present invention clearly differs from that of Morris. As noted, in claim 1, there is provided a *reaction mixture* containing the sample and the light-emitting moiety, and if necessary, other reagents. In claim 7, as amended, the light-emitting moiety is added to a colorimetric or turbidimetric *assay mixture*. In contrast, Morris does not add a fluorescent moiety or light-emitting moiety to a reaction mixture, but rather provides the fluorescent moiety embedded in a matrix. See, for example, column 10, lines 40-42; and column 4, lines 18-22, and lines 58-64. Thus, while in the present invention, the light-emitting moiety is included in the reaction mixture; in the method of Morris, it is separate therefrom and included in a solid matrix. The method of the invention is thus considerably more convenient than that of Morris which requires separate special treatment of the light emitting moiety.

In addition, because the light emitting moiety is included within the reaction mixture (unlike the matrix-contained separate light emitter of Morris) the assay is more flexible since in addition to an indicator which simply absorbs emitted light, the indicator of the analyte concentration can also be a component which physically interacts with the light emitting moiety. This permits greater assay sensitivity and convenience as well. Clearly the method of Morris could not include this alternative form of indicator.

Morris therefore does not anticipate the invention as claimed.

The Rejection Under 35 U.S.C. § 112, Paragraph 1

The Office asserts that the specification is enabling only for a single analyte, glucose. It is not clear on what basis this assertion is made. First, glucose is not the only analyte exemplified in the specification. Tables 1 and 2 set forth the results obtained when comparing a standard Lowry colorimetric determination of protein with the results obtained using the method of the invention. Second, applicant fails to see why the *Wands* factors should not be decided in favor of applicant. There is no evidence provided that the enablement requirements are not met.

It is certainly true that a wide variety of analytes, a wide variety of light-emitting moieties, and a wide variety of light-absorbing moieties could be used in the invention, but these are clearly within the purview of the ordinarily skilled artisan. The Office asserts that much experimentation is necessary because of the large proportion of inoperative compounds claimed. What inoperative compounds? There is no evidence of record that any particular compounds are inoperative.

As to the direction or guidance provided, colorimetric and turbidimetric assays for a wide variety of substances have been routinely used for at least 40 years. It should not be necessary for applicant to enumerate the plethora of compounds that are subject to such assays. And the method of the invention is simple enough – it simply requires adding a light-emitting moiety to these known reaction mixtures. In view of this, it is believed it is unnecessary to provide a multiplicity of examples. Applicant finds no basis for the assertion that the invention is complex and unpredictable; it is extremely simple. It requires only adding a light-emitting moiety to already known colorimetric or turbidimetric assays.

It is unclear on what basis it is stated that the prior art indicates that most related substances are not effective for the claimed functions. There is no prior art cited for this proposition, and

applicant is aware of none. There also seems to be no basis for the statement that the “predictability of the art is unpredictable”. While it is true that the claims encompass many possible analytes, many possible analytes are already routinely used in colorimetric and turbidimetric assays.

Respectfully, it is not believed that the Office has adduced any evidence to show that the claims are not enabled in their full scope by the specification.

The Rejection Under 35 U.S.C. § 112, Second Paragraph

It is believed that the amendment is completely responsive to this basis for rejection.

Informalities

The headings in the specification are those standard for PCT applications. In any event, no particular format is required. Further, applicant believes the title of the invention is descriptive. Short of a very wordy title, applicant is at a loss to propose a more meaningful title. Applicant would be happy to accept any suggestions made by the Office in this regard.

Conclusion

It has been demonstrated that the claimed subject matter is not anticipated by Morris, the sole document applied, because the light-emitting moiety is included in the reaction mixture, not set aside in a matrix separate therefrom. This permits a more convenient assay, and also permits an alternative form of light emission inhibition which involves physical interaction between an indicator that is proportional to analyte concentration and the light emitting moiety. Accordingly, the claims are free of the art. No evidence has been adduced by the Office to demonstrate that the claims are not enabled in their full scope. The performance of the invention is not at all complex,

nor is it unpredictable. If the Office asserts these characteristics, is it believed evidence in support of these assertions is required.

Accordingly, claims 1-9 are in a position for allowance and passage of these claims to issue is respectfully requested. Should issues remain that might be resolved by telephone, a call to the undersigned is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 527832000420.

Respectfully submitted,

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